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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/376,380 01/23/95 BEBBINGTON

C CARPR-0030C1

ZISKA, EXAMINER

18N2/0827

SPENCER FRANK AND SCHNEIDER
SUITE 300 EAST
1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3955

ART UNIT	PAPER NUMBER
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1804
1804

12

DATE MAILED:

08/27/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/2/96

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or ~~thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 15-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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This application should be reviewed for errors.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-22 are active and examined in this Office Action.

Applicants have submitted a new declaration containing a new inventor, Dr. Wilson, but have failed to submit a petition under 37 CFR 1.48 to change or correct the inventorship. In view of the failure to file the petition, the rejections of record are maintained since applicants have not been granted benefit of the earlier filing date.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 15-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 and 22 of U.S. Patent No. 5,122,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the claims overlap. Both the patent and the application claims contain the vector having the GS gene operably linked to a weak promoter upstream from a heterologous gene operably linked to a strong promoter.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

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The rejection of claim 15 under 35 U.S.C. 102(b) as being anticipated by Wilson is maintained. The rejection is maintained since applicants have not been granted benefit of an earlier filing date.

The rejection of claims 16-22 under 35 U.S.C. 103 as being unpatentable over Wilson as applied to claim 15 above and further in view of Ringold and Foecking is maintained. Applicant's arguments, filed May 22, 1996, have been considered but not found to be persuasive. Applicants have argued that the use of different strength promoters is but one of the differences in the claimed invention; that applicants have unexpectedly found that the order of the genes and direction of transcription for each of the heterologous genes in relation to the GS gene was of the most importance and that the statements of Ringold as to the order and direction of transcription are at best ambiguous and do not address the unexpected advantages of the gene order and direction of transcription of the vectors in claims 16-22. However, Wilson discloses on page 34 that the efficiency of expression is affected by the order in that the tPA gene was more efficiently expressed when in the same orientation in the vector as the GS gene than when the two genes were in opposite orientations. Ringold discloses in column 3, lines 35-48, that the promoter for the amplifiable gene should be weaker than the promoters for the succeeding genes and that, in this manner, greater amplification may be achieved when applying the selective pressure with greater expression of the succeeding genes. Thus, Ringold achieves the same end as applicants, which is increased amplification of the desired target gene. Although applicants have argued unexpected results, Ringold clearly recognized that the order of genes was important, that the amplifiable gene should be operably linked to the weak promoter and the strong promoter to the heterologous gene. Contrary to applicant's arguments, Ringold did recognized

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the importance of the order of the genes and associated promoters having different strengths.

Applicants have argued that the cited references do not teach that the gene order and direction of transcription must be arranged to prevent transcriptional interference. However, although neither Wilson nor Ringold specifically address the problem of "transcriptional interference", Ringold in particular noted the importance of promoter strength and gene order and therefore inherently both recognized the problem and determined the solution.

Applicants have argued that nowhere in Ringold is there no mention that transcriptional interference or promoter occlusion may be a problem to be considered when designing the gene order and direction of transcription of the selectable and heterologous genes of interest and cite Ringold at column 3, lines 29-31 ("the amplifiable gene and the gene of interest may be transcribed in the same or different directions"). However, although Ringold does not specifically mention applicant's problem, Ringold discloses the same technique for increasing expression of the heterologous gene and recognizes the same features, such as gene order and promoter strength, required for the successful expression.

Applicants have argued that the unobviousness can reside in the discovery of the source of a problem and cite In re Spinnable. However, Ringold inherently recognized the problem of transcriptional interference since Ringold recognized that the order and promoter strength affected the amount of expression obtained. Ringold recognized the same problem as applicants but give the problem a different name. Whether the problem be "transcriptional interference" or "decreased expression levels", both were addressed and solved by Ringold, using the same methods such as gene order and promoter strength, as applicants.

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No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO FAX center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (30 November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-0294.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Suzanne Ziska, Ph.D., whose telephone number is (703)308-1217. In the event the examiner is not available, the examiner's supervisor, Ms. Jacqueline Stone, may be contacted at phone number (703) 308-3153.


SUZANNE E. ZISKA
PRIMARY EXAMINER
GROUP 1800